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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,091	06/04/2001	Deborah Charych	1680.002	6042

7590

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

13

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,091

Applicant(s)

CHARYCH ET AL.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 09 December 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's amendment filed 12/9/02 in Paper No. 11 is acknowledged and entered. Claims 21-52 and 54 are canceled. Claims 3, 9, 16, and 20 are amended. Claims 1-20 and 53 are pending.

Drawings

2. The proposed drawing corrections, filed on 12/09/02, have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. Further, the drawing informalities of PTO-948 noted in Paper No. 9, mailed on 9/6/02, must also be corrected. *The corrections to the drawings will not be held in abeyance.*
3. The Patent and Trademark Office no longer makes drawing changes. See 1017 O.G. 4. It is applicant's responsibility to ensure that the drawings are corrected. Corrections must be made in accordance with the instructions below.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings

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should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

4. Claims 1-20 and 53 are treated on the merit in this Office Action.

Withdrawn Rejections

5. The previous rejections under 35 USC 112, second paragraph, for claims 3, 9, 16, and 20 have been withdrawn in view of applicant's amendment of claims 3, 9, 16, and 20.

6. The previous rejections under 35 USC 102(b) as being anticipated by Weetall (*Applied Biochemistry and Technology*, 41:157-188, 1993) for claims 1-4, 6 and 53 have been withdrawn in view of applicant's argument that Weetall does not disclosed a nonpeptide synthetic peptidomimetic.

7. The previous rejections under 35 USC 102(b) as being anticipated by anticipated by Sundberg et al. (US Patent 5,624,711) for claims 1-7, 9-14, and 17-18 have been withdrawn in

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view of applicant's argument that Sundberg et al. does not disclosed a nonpeptide synthetic peptidomimetic.

8. The previous rejections under 35 USC 103(a) as being obvious over Sundberg et al. (US Patent 5,624,711) in view of Barrett et al (US Patent 5,482,867) for claims 8, 14-16, and 19-20 have been withdrawn in view of applicant's.

9. Therefore, upon further consideration, the following new grounds of rejection are made as follows. Therefore, this Office action is a non-final rejection.

New Rejections

Claim Objections

10. Claim 53 is objected to because of the following informalities: The method of use limitation of claim 53 referred to a cancelled claimed that is claim 43. Appropriate correction is required.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-3, 5-6, and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Pease et al. (US Patent 5,831,070).

Pease et al. teach an apparatus comprise a substrate with an array of polymers such as peptide analogs and oligonucleotides (col. 1, lines 52-57; col. 6, lines 4-54). The substrate is flat and comprise of silicon or glass surface (col. 8, lines 44-54; col. 12, lines 2-12). The surface of the solid substrate contain reactive groups (anchoring segment) such as amino (col. 12, lines 19-23). The substrate includes a surface with a layer of linker (linker segment) (col. 10, lines 24-28; col. 12, lines 31-35). Therefore, the apparatus of Pease et al. anticipates the presently claimed invention.

Further, the limitation of “*a kit for use in performing a differential binding assay according to claim 43*” in claim 53 ^{is} ~~should~~ not be considered as limitations for this apparatus because these limitations represent functional language describing a use of the apparatus. See MPEP § 2114:

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Therefore, “*a kit for use in performing a differential binding assay according to claim 43*” has no patentable weight.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-7, 9-10, 12, 17-18, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US Patent 6,406,921 B1) in view of Pease et al. (US Patent 5,831,070).

Wagner et al. teach an array of proteins comprising a plurality of patches in discrete, known regions on a substrate, where a protein with different, known sequence is immobilized on each patch (col. 3, lines 26-29). The protein is refers to a polymer of amino acid that also include amino acid polymers in which one or more amino acid residues is an artificial chemical analogue of a corresponding naturally occurring amino acid (col. 6, lines 1-11). The array comprises of a monolayer on the surface of the substrate and the proteins are immobilized on the monolayer (col. 8, lines 9-17). The monolayer comprise of molecules of the formula X-R-Y, wherein X is a functional group that binds R to the surface (anchoring segment), (linker segment) R is a spacer, and Y is a functional group for binding proteins onto the monolayer. They are three major classes of monolayer formation are preferably used to expose high densities of

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bioreactive functionalities on the array, which are alkylsiloxane monolayer, alkyl-thiol/dialkyldisulfide monolayer, and alkyl monolayer (col. 8, lines 18-41). The functional group of X includes thiol and amine group (col. 10, lines 27-36). The functional group of Y includes N-hydroxysuccinimide (col. 11, lines 39-53).

The apparatus of Wagner et al. does not expressly disclose that the protein includes peptidomimetic protein.

Pease et al. teach an apparatus comprise a substrate with an array of polymers such as peptide analogs and oligonucleotides (col. 1, lines 52-57; col. 6, lines 4-54). The substrate is flat and comprise of silicon or glass surface (col. 8, lines 44-54; col. 12, lines 2-12). The surface of the solid substrate contain reactive groups (anchoring segment) such as amino (col. 12, lines 19-23). The substrate includes a surface with a layer of linker (linker segment) (col. 10, lines 24-28; col. 12, lines 31-35).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the protein includes peptidomimetic protein as taught by Pease et al. in the apparatus of Wagner et al. One of ordinary skill in the art would have been motivated to include the protein includes peptidomimetic protein in the apparatus of Wagner et al. for the advantage of providing a more economical production, greater chemical stability, enhanced pharmacological properties, altered specificity, and reduced antigenicity (Pease: col. 6, lines 54-60). Since both Wagner et al. and Pease et al. disclose an apparatus comprising an array of protein immobilized on a substrate (Wagner: col. 3, lines 26-29; Pease: col. 1, lines 52-57).

Further, the limitation of "*a kit for use in performing a differential binding assay according to claim 43*" in claim 53 ^{is} ~~should~~ not be considered as limitations for this apparatus

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because these limitations represent functional language describing a use of the apparatus. See

MPEP § 2114:

Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Therefore, “a kit *for use in performing a differential binding assay according to claim 43*” has no patentable weight.

16. Claims 8, 11, 13-16, and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (US Patent 6,406,921 B1) in view of Pease et al. (US Patent 5,831,070) as applied to claims 1-7, 9-10, 12, 17-18, and 53 above, and further in view of Barrett et al (US Patent 5,482,867).

Wagner et al. and Pease et al. disclose an apparatus comprising an array of protein immobilized on a substrate (Wagner: col. 3, lines 26-29; Pease: col. 1, lines 52-57). The protein includes peptide analogs such as peptidomimetic (Pease: col. 6, lines 4-54). The surface of the solid substrate contain reactive groups (anchoring segment) such as amino (Pease: col. 12, lines 19-23; Wagner: col. 8, lines 9-17 and lines 18-41). The substrate includes a surface with a layer of linker (linker segment) (Pease: col. 10, lines 24-28; col. 12, lines 31-35; Wagner: col. 8, lines 9-17 and lines 18-41). Further, Wagner et al. disclose that the (anchoring segment) functional group of X includes thiol and amine group (col. 10, lines 27-36). The (linker segment) functional group of Y includes N-hydroxysuccinimide (Wagner: col. 11, lines 39-53).

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The apparatus of Wagner et al. and Pease et al. do not expressly disclose that the anchoring segment includes biotin and avidin.

Barrett et al. teaches an array of immobilized ligands on predefined regions of a surface of a solid support (col. 2, lines 36-41). The method involves attaching to the surface a caged binding member (anchor). The ligand includes peptides (col. 4, lines 34-60). The caged binding member is a biotin analog (col. 5, lines 45-56). Avidin can be immobilized onto the surface of the solid support and bind to biotin (col. 5, lines 57-65). One type of biotin analog is a biotin with N-succinimidyl and a linking group of 6-aminocaproic (NHS-lc-lc-biotin) (col. 14, lines 66-67 to col. 15, lines 1-30).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the anchoring segment includes biotin and avidin as taught by Barrett et al. in the apparatus of Wagner et al. and Pease et al. One of ordinary skill in the art would have been motivated to include the anchoring segment includes biotin and avidin in the apparatus of Wagner et al. and Pease et al. for the advantage of providing an efficiently and stably attaching a broad range ligands on predefined regions of a solid support (Barrett: col. 2, lines 26-32). Since both Wagner et al. Pease et al and Barrett et al. disclose an apparatus comprising an array of biomolecules such as protein immobilized on a substrate (Wagner: col. 3, lines 26-29; Pease: col. 1, lines 52-57; Barrett: col. 2, lines 36-41).

Further, the limitation of “*a kit for use in performing a differential binding assay according to claim 43*” in claim 53 should not be considered as limitations for this apparatus because these limitations represent functional language describing a use of the apparatus. See MPEP § 2114:

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Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959). “[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). (emphasis in original)

A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Therefore, “*a kit for use in performing a differential binding assay according to claim 43*” has no patentable weight.

Response to Arguments

17. Applicant's arguments with respect to claims 1-20 and 53 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
February 19, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER